10/573210

IAP20 Rec'd PCT/PTO 24 MAR 2006

REDUNDANT TEMPERATURE MONITORING IN ELECTROSURGICAL SYSTEMS FOR SAFETY MITIGATION

BACKGROUND

1. Technical Field

The present invention is directed to electrosurgical systems, and, in particular, to a redundant temperature monitoring system and method for an electrosurgical system for safety mitigation.

2. Description of the Related Art

Electrosurgical generators are employed by surgeons in conjunction with an electrosurgical tool to cut, coagulate, desiccate and/or seal patient tissue. High frequency electrical energy, e.g., radio frequency (RF) energy, is produced by the electrosurgical generator and applied to the tissue by the electrosurgical tool. Both monopolar and bipolar configurations are commonly used during electrosurgical procedures.

Electrosurgical generators typically include power supply circuits, front panel interface circuits, and RF output stage circuits. Many electrical designs for electrosurgical generators are known in the field. In certain electrosurgical generator designs, the RF output stage can be adjusted to control the RMS (root mean square)

output power. The methods of controlling the RF output stage may include changing the duty cycle, or changing the amplitude of the driving signal to the RF output stage. The method of controlling the RF output stage is described herein as changing an input to the RF output stage.

Electrosurgical techniques have been used to seal or fuse small diameter blood vessels, vascular bundles and tissue. In this application, two layers of tissue are grasped and clamped together while electrosurgical power is applied. By applying a unique combination of pressure, gap distance between opposing seal surfaces and controlling the electrosurgical energy, the two tissue layers are welded or fused together into a single mass with limited demarcation between tissue layers. Tissue fusion is similar to vessel sealing, except that a vessel or duct is not necessarily sealed in this process. For example, tissue fusion may be used instead of staples for surgical anastomosis. Electrosurgical power has a desiccating effect on tissue during tissue fusion or vessel sealing.

One of the issues associated with electrosurgical sealing or fusion of tissue is undesirable collateral damage to tissue due to the various thermal effects associated with electrosurgically energizing tissue. The tissue at the operative site is heated by electrosurgical current typically applied by the electrosurgical instrument. Healthy tissue adjacent to the operative site may become thermally damaged if too much heat is allowed to build up at the operative site or adjacent the sealing surfaces. For example, during sealing, the heat may conduct or spread to the adjacent tissue and cause a

significant region of tissue necrosis. This is known as thermal spread. Thermal spread becomes important when electrosurgical instruments are used in close proximity to delicate anatomical structures. Therefore, an electrosurgical generator that reduced the possibility of thermal spread would offer a better opportunity for a successful surgical outcome.

Another issue associated with electrosurgical tissue sealing or tissue fusion is the buildup of eschar on the surgical instrument. Eschar is a deposit which is created from tissue that is charred by heat. Surgical tools often lose effectiveness when coated with eschar.

Conventional electrosurgical systems have employed temperature sensors in the surgical tool to monitor conditions at the operative site and/or the temperature of the tissue being manipulated. An exemplary temperature sensor used in such systems is a thermocouple due to its small size and low cost. However, thermocouples require compensation circuitry to achieve a desired level of accuracy, which increases the complexity of the temperature monitoring circuit and introduces additional possible points of failure. For example, if a compensation circuit fails, the electrosurgical system will still read a temperature, although possibly wrong. A technician or physician may increase output power believing they have not reached a critical temperature while actually applying too much power to the operative site causing damage to tissues and surrounding anatomical structures.

Therefore, it would be desirable to have a temperature monitoring circuit for an electrosurgical system for accurately determining a temperature of an operative site and/or tissue of a patient. Furthermore, it would be desirable to have a temperature monitoring circuit for controlling an electrosurgical generator for producing a clinically effective output and, in addition, for detecting failures of the temperature measurement circuit.

SUMMARY

A redundant temperature monitoring system and method for an electrosurgical system are provided.

According to an aspect of the present dislcosure, a temperature monitoring circuit inlcudes at least one temperature sensor for sensing a temperature at a measuring point, a first temperature measurement circuit coupled to the at least one temperature sensor for generating a first temperature value, a second temperature measurement circuit coupled to the at least one temperature sensor for generating a second temperature value, and a control circuit for determining a difference between the first and second temperature values and for comparing the difference to a first predetermined threshold. If the difference is greater than the first predetermined threshold, the control circuit generates a warning signal. If the difference is greater than a second predetermined threshold, the control circuit generates an alarm signal and/or shuts down a power source.

According to another embodiment of the present disclosure, an electrosurgical generator is provided comprising a radio frequency (RF) output circuit for outputting RF energy; a control circuit for controlling the output of the RF output circuit; and a temperature monitoring circuit comprising at least one temperature sensor for sensing a temperature at a measuring point, a first temperature measurement circuit coupled to the at least one temperature sensor for generating a first temperature value, a second temperature measurement circuit coupled to the at least one temperature sensor for generating a second temperature value, and a control circuit for determining a difference between the first and second temperature values and for comparing the difference to a first predetermined threshold. If the difference is greater than the first predetermined threshold, the control circuit generates a warning signal and, if the difference is greater than the second predetermined threshold, the control circuit generates an alarm signal.

Preferably, the electrosurgical generator further comprises a display for displaying the warning and/or alarm signal. Furthermore, the electrosurgical generator may comprise an audio output for audibly producing the warning and/or alarm signal.

According to yet another embodiment of the present disclosure, an electrosurgical system includes an electrosurgical generator for outputting radio frequency (RF) energy; an electrosurgical instrument coupled to the electrosurgical generator for applying the RF energy to an operative site; and a temperature monitoring circuit comprising at least one temperature sensor for sensing a temperature at a

measuring point, a first temperature measurement circuit coupled to the at least one temperature sensor for generating a first temperature value, a second temperature measurement circuit coupled to the at least one temperature sensor for generating a second temperature value, and a control circuit for determining a difference between the first and second temperature values and for comparing the difference to a first predetermined threshold. Furthermore, the electrosurgical instrument includes as least one end effector member and the at least one temperature sensor is located in the at least one end effector member.

In a further aspect of the present invention, a method for controlling an electrosurgical system is provided. The method comprises the steps of reading a first temperature value at an operative site; reading a second temperature value at the operative site; determining a difference of the first and second temperature values; determining if the difference is greater than a first predetermined threshold, wherein when the difference is greater than the first predetermined threshold, generating a warning signal. The method further comprises the step of, wherein when the difference is greater than a second predetermined threshold, generating an alarm signal. Additionally, the method comprises the step of shutting down the electrosurgical system when the difference is greater than a second predetermined threshold.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other aspects, features, and advantages of the present invention will become more apparent in light of the following detailed description when taken in conjunction with the accompanying drawings in which:

FIG. 1 is a block diagram of a redundant temperature monitoring system according to an embodiment of the present invention;

FIG. 2 is a schematic diagram of an exemplary thermocouple measurement circuit in accordance with the present invention;

FIG. 3 is a flowchart illustrating a method for monitoring temperature in an electrosurgical generator according to an embodiment of the present invention;

FIG. 4 is a block diagram of a redundant temperature monitoring system according to another embodiment of the present invention; and

FIG. 5 is an exemplary electrosurgical system employing a redundant temperature monitoring system in accordance with the present invention.

DETAILED DESCRIPTION

Embodiments of the present invention will be described herein below with reference to the accompanying drawings. In the following description, well-known functions or constructions are not described in detail to avoid obscuring the invention in unnecessary detail. In the figures, like reference numerals represent like elements.

A redundant temperature monitoring system and method for an electrosurgical system are provided. Redundant temperature monitoring for medical devices using temperature as a control parameter will provide a safety mitiagtor should one of the monitoring or measurement circuits fail or malfunction. Redundant measurement circuits will read temperatures at a measuring point and lead the temperatures into a control circuit for controlling the electrosurgical system. If the values read from the redundant measurement circuit diverge from one another by more than a specified amount, the control circuit or device will recognize a discrepancy and take the appropriate course of action, e.g., alarm, warn, shutdown.

Referring to FIG. 1, a redundant temperature monitoring system 100 according to an embodiment of the present invention is provided. The system 100 includes a first temperature sensor 102, a first temperature measurement circuit 104, a second temperature sensor 108, a second temperature measurement circuit 110 and a control circuit 106. The first temperature sensor 102 is electrically coupled to the first temperature measurement circuit 104 and will send a first electrical signal indicative of a temperature sensed at a measuring point to the control circuit 106. Likewise, the second

temperature sensor 108 is electrically coupled to the second temperature measurement circuit 110 and will send a second electrical signal indicative of a temperature sensed at the measuring point to the control circuit 106. The control circuit 106 will determine a difference between the first and second temperatures sensed. Additionally, the control circuit will compare the difference to a plurality of thresholds and will initiate an appropriate action depending on the magnitude of the difference.

The first and second temperature sensors 102, 108 may be any known temperature sensor in the art, for example, a thermocouple, thermistor, resistance temperature detector (RTD), semiconductor thermometer device, etc. It is to be appreciated that the temperature measurement circuit 104, 110 will be matched to the type of temperature sensor being employed.

Referring to FIG. 2, an exemplary temperature sensor 202 and temperature measurement circuit 204 is shown. The temperature measurement circuit shown in FIG. 2 is described in copending U.S. Patent Application Serial No. __/___,___, (Attorney Docket No. 11758(203-3796)) entitled "THERMOCOUPLE MEASUREMENT CIRICUT," by Derek M. Blaha, filed herewith, which is incorporated by reference herein in its entirety and assigned to the common assignee of the present invention. The thermocouple measurement circuit 204 generally includes a thermocouple input 202 for sensing a temperature of a measuring point, a compensation circuit 14 for compensating thermocouple effects of junctions of the thermocouple 202 and an instrumentation amplifier 16 for summing an output of the thermocouple and an output

of the compensation circuit and outputting a voltage indicative of the temperature sensed. The thermocouple measurement circuit 204 may also include a filtering circuit 18 for eliminating noise from the thermocouple input 202 and an offset 20 and gain 22 circuit for scaling an output of the thermocouple measurement circuit 204. A power supply circuit 31 is employed to provide a high voltage output, e.g., +15VDC, and a low voltage output, e.g., -15VDC, for energizing any component requiring power in the thermocouple measurement circuit 204. Optionally, the thermocouple measurement circuit 204 may include analog-to-digital converter for converting the analog output voltage to a digital signal.

As a further example, if a resistance temperature device (RTD) is employed as the temperature sensor, the temperature measurement circuit will include a current source to pass current through the RTD and a voltage reading means to read the voltage-drop produced across the RTD. From the current and voltage, a resistance value can be derived which is indicative of the temperature being sensed.

The control circuit 106 receives the electrical signal indicative of a temperature sensed from each of the first and second temperature measurement circuits 104, 110. The control circuit determines a difference between the temperature values received from the first and second temperature measurement circuit. The control circuit compares the difference to a plurality of threshold to determine if the temperature measurement circuits 104, 110 are operating correctly. The control circuit 106 may be a hardwired device such as a field-programmable gate array (FPGA) or programmable

logic device (PLD), or a microprocessor including necessary software modules to perform the above described functions. Upon a result of the comparison, the control circuit 106 may generate a warning or alarm signal and/or may initiate routines to control an output of a heat generating device or power source.

An operation of the redundant temperature monitoring system will now be described with reference to FIG. 3. In step 302, a first temperature value is read by the first temperature sensor 102 and sent to the control circuit 106 via the first temperature measurement circuit 104. In step 304, a second temperature value is read by the second temperature sensor 108 and sent to the control circuit 106 via the second temperature measurement circuit 110. In step 306, the control circuit 106 determines a difference between the first and second temperature values.

The temperature difference is then compared to a plurality of thresholds. In step 308, the temperature difference is compared to a first predetermined threshold. The first predetermined threshold represents a minimum allowable deviation of the measured temperatures. If the temperature difference is greater than the first predetermined threshold, the control circuit 106 generates a warning to a user of the system indicating there may be a problem with one of the temperature measuring circuits 104, 110 (step 310) and then continues to monitor the first and second temperature values. If the temperature difference is less than the first predetermined threshold, the system continues to monitor the temperature at the measuring point.

Furthermore, the control circuit 106 compares the temperature difference to a second predetermined threshold (step 312). The second predetermined threshold is a maximum allowable deviation of the measured temperatures. If the temperature difference is greater than the second predetermined threshold, the control circuit 106 generates an alarm to the user indicating that there is a problem with the temperature measurement circuits 104, 110 (step 314). Additionally, the control circuit 106 may shut down or take control of a source of the heat generation, e.g., a power source.

It is to be appreciated that the redundant temperature monitoring system of the present invention may be implemented in numerous ways within the spirit and scope of the present invention. Referring to FIG. 4, another embodiment of the redundant temperature monitoring system is illustrated. The system 400 of FIG. 4 includes a temperature sensor 402, first and second temperature measurement circuits 404, 410 and control circuit 406. Here, the first and second temperature measurement circuits 404, 410 simultaneously read the same, single temperature sensor 402. The system 400 uses less space at the measuring point due to its single temperature sensor and requires less wiring, therefore, simplifying the system 400.

An exemplary electrosurgical system 500 employing a redundant temperature monitoring system in accordance with the present invention is shown in FIG. 5. The system 500 can be used for sealing vessels 530 and other tissues of a patient, including ducts, veins, arteries and vascular tissue. The system 500 includes an electrosurgical generator 512 and a surgical instrument 514. The surgical instrument 514 is illustrated

by way of example, and as will become apparent from the discussion below, other instruments can be utilized. The electrosurgical generator 512 includes several interconnected sub-units, including an RF output circuit 516, a control circuit 506, a variable D.C. power supply 518 and first and second temperature measurement circuits 504, 510. It is to be understood that the control circuit 506 controls the overall functions of the electrosurgical generator 512, in addition, to determining the difference of the first and second temperature values and comparing the difference to the plurality of thresholds. In other embodiments, a separate control circuit may be provided to perform the determining and comparing functions with its result being sent to another separate control circuit for controlling the overall functions of the electrosurgical generator.

Additionally, the electrosurgical generator 512 may include a display 520 for displaying temperature values, output power values, alarms, etc. The display 520 may take the form of LEDs, a liquid crystal display or any known display in the art. Furthermore, the electrosurgical generator may include an audio output 522, such as a speaker, for alerting a user, who for example may be performing a procedure an a patient and not observing the display.

The surgical instrument 514 is electrically connected to the electrosurgical generator 512 via cable 524 for receiving controlled electrosurgical power therefrom. The surgical instrument 514 has some type of end effector member 526, such as a forceps or hemostat, capable of grasping and holding the vessels and tissues of the patient. The member 526, also referred to simply as end effector 526, is assumed, in

this embodiment, to be capable of applying and maintaining a relatively constant level of pressure on the vessel 530.

The member 526 is provided in the form of bipolar electrosurgical forceps using two generally opposing electrodes disposed on inner opposing surfaces of the member 526, and which are both electrically coupled to the output of the electrosurgical generator 512. During use, different electric potentials are applied to each electrode. Since tissue is an electrical conductor, the electrical energy output from the electrosurgical generator 512 is transferred through the intervening tissue. Both open surgical procedures and endoscopic surgical procedures can be performed with suitably adapted surgical instruments 514. It should also be noted that the member 526 could be monopolar forceps that utilizes one active electrode, with the other (return) electrode or pad being attached externally to the patient, or a combination of bipolar and monopolar forceps.

Temperature sensor 502 is preferably located in member 526 to measure the temperature of the patient tissue or of the operative site. In the embodiment shown in FIG. 5, one temperature sensor 502 is coupled to the first and second temperature measurement circuits 504, 510. In further embodiments, a temperature sensor may be provided for each temperature measurement circuit. The redundant temperature sensors at be positioned at the same location or one may be positioned in each end member 526.

The temperature sensor 502 is coupled to the temperature measurement circuits 504, 510 via cable 524. An output signal indicative of the temperature at the temperature sensor 502 is sent to the control circuit 506 from each of the first and second temperature measurement circuits 504, 510. The control circuit 506 then determines the difference between the first and second temperature values. The difference is then compared to a plurality of thresholds. If the difference is greater than a first predetermined threshold, the control circuit 506 generates a warning signal to be displayed on the display 520 and/or audibly produced at the audio output 522.

If the difference is greater than a second predetermined output, the control circuit 506 generates an alarm signal to be displayed on the display 520 and/or audibly produced at the audio output 522. Additionally, the control circuit 506 either shuts down the power supply 518 to effectively stop power from being output to the surgical tool 514 or adjust the output power to a lower level.

It is to be appreciated that output power from the electrosurgical generator can be adjusted in several ways. For example, the amplitude of the output power can be adjusted. In another example, the output power can be adjusted by changing the duty cycle or the crest factor.

In another embodiment, it is contemplated that the control circuit 506 controls a module for producing resistive heat for regulating heat applied to the tissue for achieving a desired tissue effect instead of or in addition to controlling the

electrosurgical output circuit 516 and/or the power supply 518. The control circuit 506 responds to sensed tissue temperature indicative of tissue temperature and outputs a command signal for controlling output heat resistivity. Preferably, the module for producing resistive heat includes a current source and/or a variable resistor which are responsive to the command signal for outputting a desired current or providing a desired resistance, respectively. In this embodiment, if the temperature difference is greater than the second predetermined threshold, the control circuit 506 will control the module for producing resistive heat.

While several embodiments of the disclosure have been shown in the drawings, it is not intended that the disclosure be limited thereto, as it is intended that the disclosures be as broad in scope as the art will allow and that the specification be read likewise. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments.